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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,494	03/08/2002	Samuel D. Bernal	344-P-29-CIPUSA	1407

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,494

Applicant(s)

BERNAL ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step (or steps) that provide for the detection of marking agent being taken up by the mitochondria. For example, a step such as, detecting cancerous epithelial cells *in vivo* under UV light to detect fluorescence of the agent, is required.

Claim 3 recites the limitation "the agent" in line 1. There is insufficient antecedent basis for this limitation in the claim. The recitation of "the agent" in line 1 of claim 3 lacks antecedent basis and is confusing. The recitation of "the agent" in line 1 of claim 3 refers back to claim 2, which defines the agent as "a cationic supravital mitochondrial-marking agent" but claim 3 defines the same "agent" (of claim 2) as "a cationic supravital mitochondrial marking agent and a cancer therapeutic agent." It is unclear how "the agent" of claim 2 can be defined as the "agent" as well as the agent plus a chemotherapeutic agent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernal (Science, Vol. 222, 8/1983).

Bernal discloses a method of *in vivo* detection of cancerous epithelial cells comprising administering a cationic mitochondrial marking agent (Rh123) and detecting tumor cells using

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immunofluorescence, see page 169. Bernal also discloses a method of selective killing of epithelial cancer cells by administering "a cationic supravital mitochondrial marking agent" (Rh123), see page 170. Bernal further discloses a method of killing cancers cells using "a cationic supravital mitochondrial marking agent" and a chemotherapeutic (i.e., 2-deoxyglucose), see page 170. Note that rhodamine is within the scope of cationic supravital mitochondrial marking agent as defined on pages 7-8, as "dyes," and therefore would be expected to meet the functional limitations set forth in the dependent claims. Since applicant defines the agent to include dyes, such dyes must have the same properties as defined in the dependent claims.

Claims 1 and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Malmros (US 5,372,801).

Malmros discloses a method of detection of epithelial cancers comprising administering a cationic supravital mitochondrial marking agent, the fluorescent dye, toluidine blue O, see abstract and column 2. Note that toluidine blue O is within the scope of cationic supravital mitochondrial marking agent, as this dye is specifically defined as such on pages 7-8 of the instant specification. Thus, this dye would be expected to inherently meet the functional limitations set forth in the dependent claims. Since applicant defines the agent to include toluidine blue O, this dye must have the same properties as defined in the dependent claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernal (Science, 1983, PTO-892) in view of Hancock (US 4,816,395).

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Bernal discloses a method of *in vivo* detection of cancerous epithelial cells comprising administering a cationic mitochondrial marking agent (Rh123), as well as, a method of selective killing thereof by administering a "a cationic supravital mitochondrial marking agent" without and with a chemotherapeutic agent, as set forth above.

Bernal fails to teach the use of various chemotherapeutic agents as encompassed by the instant claims.

Hancock teaches a method of both detecting and treating cancer cells comprising administering a cancer marking agent (e.g., a fluorescent dye, etc.), which is conjugated to a chemotherapeutic agent, see columns 2-3. The conjugation of the chemotherapeutic to the dye provides the advantage of being able to detect the uptake of the chemotherapeutic drug. Hancock teaches that various chemotherapeutic drugs may be used as equivalents, see column 3, lines 3+.

It would have been obvious to one of ordinary skill in the art to modify the methods disclosed by Bernal to include various equivalent chemotherapeutic drugs because Hancock teaches that various chemotherapeutic drugs may be conjugated to dyes in an equivalent manner to provide the desired chemotherapeutic effect and to provide a means of tracking the uptake of various chemotherapeutic drugs after administration.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/673,991.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to methods that are completely within the scope of the claims of the '991 application. The instant claims are generic to the claims of the '991 application in that they are generic to the means of administration (and detection), while the '991 claims require topically administering the mitochondrial marking agent and that the retention of the agent in the mitochondria is detected. The '991 claims also exclude toluidine blue, while the instant claims are generic to the agent. Thus, since the instant claims are generic to the method of the '991 claims, but are drawn to the same methods and administration of the same agents, the instant claims are fully encompassed, that is, anticipated by the claims of the '991 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Michael G. Hartley
Primary Examiner
Art Unit 1616

10/28/2003